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(56) Documents Cited

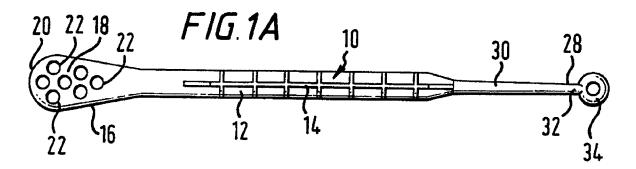
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UK CL (Edition M) A4V , A5B BZ , A5R RCX REW REY
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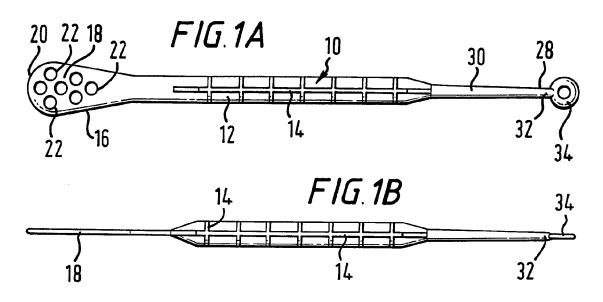
(54) Apparatus for self-administration of a medicament

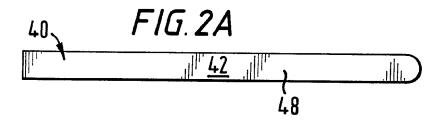
(57) Apparatus which allows the self-administration of a medicant to parts of the body not readily accessible or visible is disclosed. The apparatus is intended for the self-treatment of e.g. genital warts and comprises a spatula 10 and a separate mirror. The spatula has loops or holes at its ends which retain the liquid medicant to be applied. The mirror has a pivotted lid which can also act as a stand.

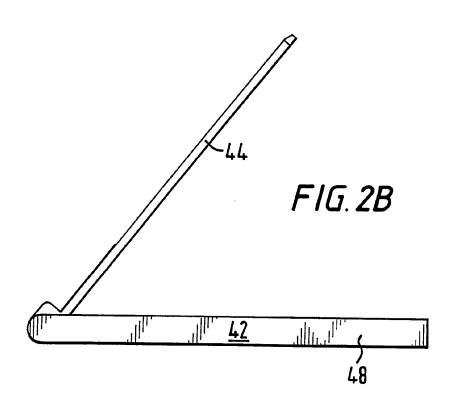


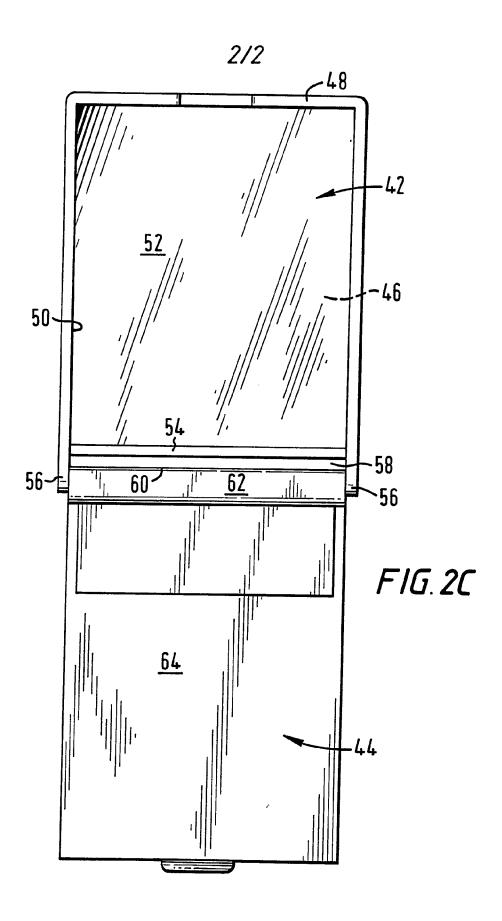
At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.









- 1 -

APPARATUS FOR SELF-ADMINISTRATION OF A TOPICAL

MEDICAMENT

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DESCRIPTION

The present invention relates to apparatus for self-administration of a topical medicament and has particular reference to apparatus for applying a cytotoxic medicament to parts of the body which are not easily accessible and/or visible to the patient.

podophyllotoxin is well established as a topical medicament for the treatment of penile and vaginal warts; typically, podophyllotoxin is formulated as a 0.5% w/v solution in a pharmaceutically acceptable liquid carrier. Podophyllotoxin is one of a class of pharmaceutically active agents known as cytotoxic agents which have a destructive action on particular cells; podophyllotoxin, in particular, has a destructive action on the tumour-like cells which constitute warts.

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It will be appreciated by a person skilled in the art, however, that great care must be exercised when administering a cytotoxic medicament topically to a patient. It is desirable that only those specific cells to be destroyed are contacted with cytotoxin, and care is taken to ensure that the surrounding healthy cells are not damaged.

Accordingly, it has hitherto been necessary for a patient suffering from a complaint which requires the topical administration of a medicament on a part of the body which is not easily accessible and/or visible to the patient to obtain the assistance of a medical professional in applying the medicament. In the case of women patients suffering from vaginal warts, for example, it has hitherto been necessary for them to visit their family doctor or a specialised clinic for treatment. It will be understood that this generally inconvenient for most patients since, at best, it results in making a special trip to the medical professional concerned and, at worst, it results in lost working hours. As a result, it has found that patient compliance in obtaining been treatment for such complaints is generally low.

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There is therefore a requirement for apparatus for permitting self treatment of medical complaints such for example as vaginal warts which requires the topical administration of a medicament in an area of the body which is not easily accessible and/or visible.

According to one aspect of the present invention there there is provided apparatus for self-administration of a topical medicament, said apparatus comprising a mirror which can be positioned to assist the patient in viewing an area of the body to be treated and an applicator for applying the medicament to said area.

The provision of the mirror may allow the patient to view more clearly the part of the body to be treated and thus the accuracy with which the topical medicament is applied to the area may be significantly improved. Furthermore, the present invention may permit self-treatment by a patient in his/her own home; patient compliance may therefore be increased.

In some embodiments, the mirror may include a stand for supporting the mirror on a surface. This may leave the patient with both hands free for applying said topical medicament.

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In one aspect, the mirror may further comprise hinge means between the stand and a mirrored portion of the mirror such that the stand and the mirrored portion can be pivoted one relative to the other between a first closed position in which the stand is disposed juxtaposed to the mirrored portion and a second open position in which the stand and mirrored portion subtend an angle therebetween such that the mirror can be stood on a surface. Thus, with the stand in the first closed position, a compact mirror may be provided which is more convenient for transporting e.g. in a lady's handbag.

Typically, the stand may overlay the mirror portion in the first closed position so as to protect the mirrored portion when not in use. In the second open position, the stand may extend substantially horizontally away from the hinge means relative to the surface on which the mirror stands, and the mirrored

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portion may extend generally upwards from the hinge means and may be tilted away from the vertical such that the centre of mass of the mirrored portion is disposed over the stand. It will be appreciated that with the centre of gravity of the mirrored portion disposed vertically over the stand in the second open position, a stable mirror may be provided.

In a different aspect of the invention, the applicator may be a spatula comprising a head portion which can pick-up and retain for subsequent administration a measured amount of a liquid medicament. Typically, said head portion may comprise a loop, the medicament being retained in the loop as a result of its surface tension therein.

In some embodiments, the head portion may comprise a plurality of spaced loops. Each loop may be adapted to pick up and retain an equal measured amount of said liquid medicament. In some patients suffering from wart disease, it has been observed that the warts may "proliferate" in juxtaposition and eventually fuse to form a relatively large mass of wart cells. The provision of a multi-looped head portion may therefore

allow the administration of said medicament to the whole or a major portion of such a fused mass of wart cells in "one hit". The spacing of the loops may be substantially the same as the mean spacing between the warts comprised by the large fused wart mass.

Typically, the head portion is substantially planar having a plurality of holes extending therethrough so as to define said spaced loops.

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In another aspect of the invention, said applicator may be a double headed spatula having a first head having a single loop and a second head having a plurality of loops. Said spatula may comprise an elongate handle portion intermediate said first and second heads.

The present invention also embraces a kit for the self-treatment of vaginal warts comprising apparatus in accordance with the invention and a topical, liquid medicament containing a cytotoxic agent in a pharmaceutically acceptable carrier therefor. Typically, said cytotoxic agent may be

podophyllotoxin; said liquid medicament may contain 0.5% w/v podophyllotoxin.

Following is a description by way of example only and with reference to the accompanying informal drawings of methods of carrying the present invention into effect.

In the drawings:-

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Figure 1A is a plan view of a spatula for the topical administration of a liquid medicament.

Figure 1B is a side view of the spatula of Figure 15 1A.

Figure 2A is a side view of a mirror for assisting a patient in viewing an area of the body to be treated, the mirror being arranged in a first closed position.

Figure 2B is a side view of the mirror of Figure 2A in a second open position.

Figure 2C is a plan view of the mirror of Figures 2A and 2B as shown in an intermediate position.

A kit for the self administration of podophyllotoxin 0.5% w/v to vaginal warts comprises a plurality of spatulas, a mirror and a bottle of podophyllotoxin 0.5 w/v formulated in a pharmaceutically acceptable carrier.

10 Each spatula (10) is formed as a single piece from a thermoplastics material. Said spatula (10) comprises an elongate handle portion (12) which is stiffened by a plurality of longitudinal and transverse ribs (14). At one end (16) the spatula (10) is formed with a 15 substantially planar head portion (18) which widens out from the handle portion (12) and has an arcuate edge (20) at its extremity. The head portion (18) has a plurality of spaced circular apertures extending therethrough which define a plurality of spaced 20 "loops" (22); the apertures are substantially equi-sized.

At its other end (28), the spatula (10) is formed with an elongate stem (30) which terminates at its extremity (32) in a single loop (34) constituted by a taurus.

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In use, one or other end (16,28) is dipped into the podophyllotoxin solution, and a measured amount of said solution is picked up and retained by each loop (22, 34) as a result of its surface tension. In order to apply the medicament to an area of a body to be treated, the end of the spatula carrying the medicament is "touched" onto said area thereby delivering the medicament.

- The one end (16) of the spatula is suitable for the application of podophyllotoxin solution to a mass of fused warts, the other end (32) is suitable for applying the medicament to a single wart.
- The mirror (40) can be used to assist the patient in viewing the area of the body to be treated; for example, in the treatment of vaginal warts with podophyllotoxin 0.5% w/v, the mirror can be positioned by a women patient to view the infected part of the

vagina. Said mirror (40) comprises a rectangular mirror holding part (42) and a lid (44) which constitutes a stand.

Said mirror holding part (42) is moulded as a single piece from a thermoplastics material and includes a rectangular backing sheet (46) which is formed on one surface with a peripheral raised rim (48) which defines a mirror cavity (50) in juxtaposition with the one surface of the backing sheet (46); said mirror cavity (50) accommodates a rectangular mirror sheet (52) e.g. a glass/foil laminate of the kind well known to a person skilled in the art.

Juxtaposed one side (54) of the mirror cavity (50), the mirror holding part (42) is formed with two spaced arms (56) which protrude in the plane of the mirror holding part (42) to define a longitudinal recess (58) therebetween.

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Said recess accommodates a corresponding side (60) of the lid (44), which side (60) is formed with a thickened bar (62) which extends between said arms (56), each arm (56) is joined to an end of said bar (62) by a hinge pin (not shown) such that the lid and mirror holding part (42) can pivot one with respect to the other about said hinge pins.

5 The remainder of the lid (44) is constituted by a substantially rectangular sheet (64) which is formed integrally with the bar (62) and is dimensioned such that in a first closed position (see Figure 2A) with the mirror holding part (42) and lid (44) in juxtaposition, the sheet (64) is accommodated in the mirror cavity (50) flush with the peripheral ridge (48) so as to overlay and protect the mirror sheet (52) when the mirror is not in use.

The lid (44) can be pivoted about said hinge pins from the first closed position through about 300° to a second open position (see Figure 2B) in which the other side of the backing sheet (46) of the mirror holding portion (42) juxtaposed with said one side (54) abuts on the other side of the lid (44) thereby preventing further relative movement between the lid and the mirror holding portion (42) away from the first closed position. In the second open position, the mirror can be stood on a surface with the lid (44)

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lowermost constituting a stand (with the one surface of the lid 44 facing downwardly), and the mirror holding portion (42) extending generally upwardly from the hinge and being tilted back slightly as shown in Figure 2B such that the centre of the gravity of the mirror holding portion (42) is disposed vertically above the base portion to provide a stable assembly.

In the second position, the mirror can be placed on a surface in juxtaposition with the area of the patient to be treated thereby to assist the patient in viewing the said area when applying the topical medicament.

While the present invention has been described herein with particular reference to the treatment of vaginal wart disease, it will be appreciated that the apparatus may be used for the self-administration of a suitable topical medicament to any infected area of the body which is not easily visible to a patient e.g. the area of the anus.

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CLAIMS

1. An apparatus for self-administration of a topical medicament, said apparatus comprising a mirror which can be positioned to assist a patient in viewing an area of the body to be treated and an applicator for applying the medicament to said area.

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- An apparatus as claimed in claim 1 wherein said
 mirror includes a stand for supporting the mirror on a surface.
- 3. An apparatus as claimed in claim 2 wherein the mirror further comprises hinge means between the stand and a mirrored portion of the mirror such that the stand and the mirrored portion can be pivoted one relative to the other between a first closed position in which the stand is disposed juxtaposed the mirrored portion and a second open position in which the stand and mirrored portion subtend an angle therebetween such that the mirror can stand on a surface.
 - 4. An apparatus as claimed in claim 3 wherein the stand overlays the mirror portion in the first closed position so as to protect the mirrored portion when not in use.

5. An apparatus as claimed in claim 3 or claim 4 wherein in the second open position the stand extends substantially horizontally away from the hinge means relative to the surface on which the mirror stands in use, and the mirrored portion extends generally upwards from the hinge means and is tilted away from the vertical such that the centre of mass of the mirrored portion is disposed over the stand.

- 10 6. An apparatus as claimed in any preceding claim wherein the applicator is a spatula comprising a head portion which can pick-up and retain for subsequent administration a measured amount of a liquid medicament.
- 7. An apparatus as claimed in claim 6 wherein the head portion comprises a loop.
- An apparatus as claimed in claim 6 or claim 7
 wherein the head portion comprises a plurality of spaced
 loops.
 - 9. An apparatus as claimed in claim 8 wherein the spacing of the loops is substantially the same as the mean spacing between warts comprised by a fused wart mass.

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10. An apparatus as claimed in claim 8 or 9 wherein the head portion is substantially planar having a plurality of holes extending therethrough so as to define said spaced loops.

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11. An apparatus as claimed in any preceeding claim wherein said applicator is a double headed spatula having a first head portion having a single loop and a second head portion having a plurality of loops.

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- 12. A kit for the self-treatment of vaginal warts comprising an apparatus in accordance with any of preceding claims 1 to 11 and a topical, liquid medicament containing a cytotoxic agent in a pharmaceutically acceptable carrier therefor.
- 13. A kit as claimed in claim 12 wherein said cytotoxic agent is podophyllotoxin.
- 20 14. A kit as claimed in claim 12 or claim 13 wherein said liquid medicament contains 0.5% w/v podophyllotoxin.

Patents Act 1977 Examiner's report to the Comptroller under Section 17 The Search report)	Application number GB 9310719.1 Search Examiner MR N FRANKLIN	
Relevant Technical Fields (i) UK Cl (Ed.M) A5R (RCX, REW, REY) A4V, A5B (BZ)		
(ii) Int Cl (Ed.5) A45D 34/04; A61M 35/00	Date of completion of Search JULY 1994	
Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications.	Documents considered relevant following a search in respect of Claims:- 1-14	

Categories of documents

(ii) ONLINE DATABASE: WPI

X:	Document indicating lack of novelty or of inventive step.	P:	Document published on or after the declared priority date but before the filing date of the present application.
Y:	Document indicating lack of inventive step if combined with one or more other documents of the same category.	E:	Patent document published on or after, but with priority date earlier than, the filing date of the present application.
A:	Document indicating technological background and/or state of the art.	&:	Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)	
Y	GB 2160105 A	(HADFIELD) note fluid applicator of figures, page 4 lines 14-18	1-4, 12-14	
Y	GB 2046596 A	(GOOLAMALI) note applicator of figures, page 1 lines 5-11	1-4, 12-14	
X	GB 1321506	(MAURICE) note Claims 1, 4	1	
Y	GB 871846	(GELSINGER) note mirror of figures	1-4, 12-14	
Y	GB 545921	(LAWRENCE) note mirror of Figure 4	1-4, 12-14	
X	US 3845764	(WINDSOR) note mirror 20 and eye-dropper of Figures 1-4	1	

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